IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

BUZZIE SMITH, individually and on behalf of the Heirs and Estate of Charles A. Smith, Deceased, Plaintiff, v. TERUMO CARDIOVASCULAR SYSTEMS CORPORATION; IHC HEALTH SERVICES, INC.; INTERMOUNTAIN MEDICAL CENTER; INTERMOUNTAIN HEALTH CARE, INC., Defendants.	**MEMORANDUM DECISION AND ORDER GRANTING [149] MOTION TO EXCLUDE [PORTIONS OF] STEVE MALOSKY'S EXPERT TESTIMONY** Case No. 2:12-cv-00998-DN District Judge David Nuffer

The decedent Charles A. Smith (Mr. Smith), represented in this litigation by Buzzie Smith (Mrs. Smith), underwent surgery on his heart in September 2010. There were complications during the surgery. Eleven months later, Mr. Smith passed away. Mrs. Smith brings this action against the hospital and a manufacturer of a device used during the surgery (collectively "Defendants").[1] To establish certain elements of her claims, Mrs. Smith offers Dr. Steven Malosky's expert opinion and testimony. Defendants move (Motion) to exclude various

[1] Amended Complaint, docket no. 17, filed October 7, 2013.

portions of Dr. Malosky's opinion and testimony.[2] Mrs. Smith opposes the Motion (Opposition).[3] Defendants reply in support of the Motion.[4]

As discussed below, Dr. Malosky's opinions and testimony are not helpful or reliable and he is not qualified to render some of the opinions offered. Therefore, the Motion is GRANTED.

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BACKGROUND[5]

On September 13, 2010, Mr. Smith underwent heart valve replacement surgery (September 2010 surgery).[6] As part of the surgery, a Terumo Advanced Perfusion System 1 heart/lung bypass machine was used.[7] The bypass machine was to provide for the circulation of blood and oxygen through Mr. Smith's body while surgery was being performed on his heart

[2] Terumo Cardiovascular Systems Corporation's Motion to Exclude Steve Malosky (Motion), docket no. 149, filed May 12, 2017; Notice of Joinder in Terumo's Motion to Exclude Steve Malosky, docket no. 161, filed May 16, 2017.

[3] Plaintiff's Opposition to Terumo Cardiovascular System Corporation's Motion to Exclude Steve Malosky (Opposition), docket no 176, filed June 3, 2017.

[4] Reply Memorandum in Support of Terumo Cardiovascular Systems Corporation's Motion to Exclude Dr. Steve Malosky, docket no. 191, filed June 20, 2017.

[5] The undisputed material facts will be determined in the rulings on the motions for summary judgment. The facts described below are provided only for context and are taken as alleged in the Complaint.

[6] Complaint ¶ 11.

[7] *Id.* ¶ 12.

valve.[8] At some point, the bypass machine stopped working for 10–11 minutes.[9] After the surgery, Mr. Smith remained hospitalized.[10] And eleven months later, on August 6, 2011, Mr. Smith passed away from a myocardial infarction, (*i.e.*, heart attack).[11]

Dr. Malosky is a cardiologist hired by Mrs. Smith to offer opinions on the September 2010 surgery, the related complications, and Mr. Smith's death. In his opinion, Dr. Malosky lists various injuries he attributes to the September 2010 surgery and attendant complications:

> As a consequence of tissues within his body being deprived of proper flow of oxygenated blood for that period of time [during the September 2010 surgery], Mr. Smith sustained injuries. The heart muscle itself was injured during the procedure, with a deterioration of heart muscle strength noted following the surgery and substantial worsening of Mr. Smith's congestive heart failure syndrome. In addition, Mr. Smith suffered an injury to the brain due to prolonged lack of oxygenated blood flow to the brain. Mr. Smith was in medical facilities for approximately 2 ½ months continuously following the surgery, and he never recovered his pre-surgery level of functioning. He died August 6, 2011, 11 months following the surgery.[12]

Dr. Malosky then opines that "[i]t is more likely than not that proper and uninterrupted forward arterial flow during his heart valve replacement surgery would have prevented the above-described injuries and prolonged course of treatment with the resulting physical and mental deterioration that Mr. Smith endured prior to his death."[13] Dr. Malosky concludes that the injuries Mr. Smith suffered during "the time of the heart valve replacement surgery made him less able to tolerate and/or survive additional adverse events and medical stressors." Dr. Malosky

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[8] *Id.* ¶ 13.

[9] *Id.* ¶¶ 15–17; though the Complaint fails to specify how many minutes the bypass machine was not working, the parties seem to agree on between 10 and 11 minutes. *See* Motion at 4.

[10] *Id.* ¶ 17.

[11] *Id.*

[12] Exhibit 2 Report of Expert Opinions Rendered by; Dr. Steve Malosky (Dr. Malosky Report) at 1, docket no. 149, filed May 12, 2017. The exhibits were included in the file for the motion proper. They do not have a separate docket entry.

[13] *Id.*

later clarifies that by "additional adverse events and medical stressors" he is referring to the "myocardial infarction" that caused Mr. Smith's death.[14]

DISCUSSION

Defendants argue that portions of Dr. Malosky's testimony should be excluded for several reasons. First, Defendants argue that Dr. Malosky's "opinions related to Mr. Smith's death are unhelpful and unreliable."[15] Second, Defendants argue that "Dr. Malosky's opinions about injuries to Mr. Smith's heart are unhelpful and unreliable."[16] Third, Defendants argue that "Dr. Malosky is not qualified to opine on neurological injury, and his opinions are not helpful and not reliable."[17] And fourth, Defendants argue that Dr. Malosky should not be allowed "to provide a narrative of events that can and should be provided by other witnesses and records."[18]

Federal Rule of Evidence 702 addresses the standard for the admissibility of expert testimony.

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.[19]

"Under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable."[20] The inquiry of scientific reliability is

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[14] Deposition of Steven Anthony Malosky at 55:13–18, docket no. 185-5, filed June 14, 2017.

[15] Motion at 6.

[16] *Id.* at 9.

[17] *Id.* at 12.

[18] *Id.* at 19.

[19] Fed. R. Evid. 702

[20] *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993).

flexible and focuses on principles and methodology.[21] The Supreme Court has offered several non-exhaustive factors that a court may rely on for determining reliability such as, whether the testimony can be tested, has been peer reviewed, has a known or potential rate of error, and has attracted acceptance in the relevant scientific community.[22]

District courts serve as the gatekeepers of expert evidence, and must therefore decide which experts may testify and present evidence before the jury.[23] Courts are given "broad latitude" in deciding "how to determine reliability" and in making the "ultimate reliability determination."[24] The Federal Rules of Evidence, however, generally favor the admissibility of expert testimony.[25] Excluding expert testimony is the exception rather than the rule,[26] and often times the appropriate means of attacking shaky but admissible evidence is through vigorous cross-examination, and the presentation of contrary evidence.[27] "[T]he Federal Rules of Evidence favor the admissibility of expert testimony, and [courts'] role as gatekeeper is not intended to serve as a replacement for the adversary system."[28]

The inquiry into whether an expert's testimony is reliable is not whether the expert has a general expertise in the relevant field, but whether the expert has sufficient specialized knowledge to assist jurors in deciding the particular issues before the court.[29]

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[21] *See Id.* at 595

[22] *See Id.*

[23] *See* Id. at 579.

[24] *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 142 (1999), (citing *General Electric Co. v. Joiner*, 522 U.S. 135 (1997)).

[25] *See Daubert*, 509 U.S. at 588.

[26] *See* Fed. R. Evid. 702 Advisory Notes.

[27] *See Daubert*, 509 U.S. at 596.

[28] *THOIP v. Walt Disney Co.*, 690 F. Supp. 2d 218, 230 (S.D.N.Y. 2010).

[29] *Kumho*, 526 U.S. at 156.

Expert testimony is subject to Federal Rule of Evidence 403. "The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."[30]

In determining whether expert testimony is admissible the first step is to determine whether the expert is qualified, and then if the expert is qualified determine whether the expert's opinion is reliable by assessing the underlying reasoning and methodology.[31] If the expert is qualified and the opinion reliable, the subject of the opinion must be relevant; i.e. the opinion must "help the trier of fact to understand the evidence or to determine a fact *in issue*."[32] "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful."[33]

1. Dr. Malosky's opinions related to Mr. Smith's death are not helpful or reliable.

Defendants argue that Dr. Malosky's opinions regarding the alleged cause and effect relationship between the complications of Mr. Smith's surgery and his ultimate death should be excluded. First, Defendants argue that Dr. Malosky's testimony is not helpful because it fails "to show a valid scientific connection between his opinion and the issues of medical causation . . . . Dr. Malosky is unable to state, and does not opine, to a reasonable degree of medical probability that but for the complications during his September 2010 surgery, Mr. Smith would have died on August 6, 2011."[34] And second, Defendants argue that Dr. Malosky's methodology is flawed

[30] Fed. R. Evid. 403.

[31] *U.S. v. Nacchio*, 555 F.3d 1234, 1241(10th Cir. 2009).

[32] Fed. R. Evid. 702 (emphasis added).

[33] *Daubert*, 509 U.S. at 591.

[34] Motion at 6.

because he speaks in vague terms,[35] fails to account for Mr. Smith's preexisting conditions,[36] and because he fails to cite, consider, or rely on any literature or studies.[37]

i. Dr. Malosky's opinion is not helpful to establish medical causation.

"Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility."[38]

Mrs. Smith alleges negligence by the defendants.[39] "A prima facie case in negligence is made out in Utah upon demonstration that (1) defendant had a duty to the plaintiff; (2) defendant breached that duty; (3) defendants conduct was the cause-in-fact of the injury as well as the proximate cause [also known as legal cause]; and (4) as a result, plaintiff sustained injury."[40] "Cause in fact, or 'but for' causation, means that if the harmful result would not have come about but for the negligent conduct, then there is a direct causal connection between the negligence and the injury."[41] "For a particular negligent act to be the legal cause [i.e. proximate cause] of a plaintiff's injuries, there must be some greater level of connection between the act and the injury than mere 'but for' causation."[42] To establish proximate cause, a plaintiff "must prove that [defendant's] conduct was a substantial causative factor leading to his injury. However . . . , there can be more than one proximate cause or, more specifically, substantial causative factor, of

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[35] *Id.* at 8.

[36] *Id.*

[37] *Id.*

[38] *Daubert*, 509 U.S. at 591–92.

[39] Complaint at 3 and 8.

[40] *Andersen v. Brigham Young University*, 879 F. Supp. 1124, 1129 (D. Utah 1995) (citing *Harris v. Utah Transit Auth.*, 671 P.2d 217 (Utah 1983)).

[41] *Raab v. Utah Ry. Co.*, 221 P.3d 219, 226 n.17 (Utah 2009).

[42] *Id.* at 226.

an injury."[43] "Proximate cause is that cause which, in natural and continuous sequence (unbroken by an efficient intervening cause), produces the injury and without which the result would not have occurred. It is the efficient cause—the one that necessarily sets in operation the factors that accomplish the injury."[44] "[N]egligent conduct is not a proximate cause in bringing about harm to another if the harm would have been sustained even if the actor had not been negligent."[45]Medical causation (both but-for and proximate) must come from expert testimony.[46]

Therefore, to be helpful, Dr. Malosky's opinion and testimony that the September 2010 surgery and related complications had any causal—both but-for and proximate—relationship to Mr. Smith's injuries and ultimate death must be based on a "valid scientific connection."[47]

Dr. Malosky's deposition testimony demonstrates that his testimony is not helpful. He admits that he cannot testify with certainty that there is a causal connection between the surgery, the ten-minute lack of flow, and the heart attack that caused Mr. Smith's death:

> Q: Okay. Do you think there's a causal relationship between the events of the surgery and that myocardial infarction?
>
> A: I think that the fact -- you know, the fact that he went into the myocardial infarction in such a weakened state with worse LV function and a substantially worse congestive heart failure syndrome made it less likely that

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[43] *McCorvey v. Utah State Dept. of Transp.*, 868 P.2d 41, 45 (Utah 1993).

[44] *Crestwood Cove Apartments Business Trust v. Turner*, 164 P.3d 1247, 1256 (Utah 2007).

[45] *Proctor v. Costco Wholesale Corp.*, 311 P.3d 564, 569 (Utah Ct. App. 2013).

[46] *Fredrickson v. Maw*, 119 Utah 385, 387 (Utah 1951) (overruled on different grounds in *Swan v. Lamb*, 584 P.2d 814 (Utah 1978)) ("in those cases which depend upon knowledge of the scientific effect of medicine, the results of surgery, or whether the attending physician exercised the ordinary care, skill and knowledge required of doctors . . . , must ordinarily be established by the testimony of physicians and surgeons."); *see also Fitz v. Synthes (USA)*, 990 P.2d 391 (Utah 1999) ("This court has held that medical expert testimony is required to prove proximate cause in a medical injury case" citing *Fredrickson*); *see also Reeves v. Geigy Pharmaceutical Inc. a Div. of Cib-Geigy Corp.*, 764 P.2d 636, 640 (Utah Ct. App 1988) (for negligence claim, "expert medical testimony was required to establish causation, the standard of care, and its breach."); *see also Hoopiiania v. Intermountain Health Care*, 740 P.2d 270, 271 (Utah Ct. App. 1987) ("In medical malpractice actions the plaintiff must provide expert testimony to establish: 1) the standard of care . . . ; 2) defendant's failure to comply with that standard . . . ; and 3) that defendant caused plaintiff's injuries.").

[47] *Daubert*, 509 U.S. at 591.

> he would survive a myocardial infarction. I think that the -- the stress that he was under, the psychological stress after the incident, *played some role in increasing the odds* that he would have a heart attack or myocardial infarction. However, I would say that, as a person with underlying plaque, people who have coronary artery disease can have a myocardial infarction. *I couldn't say with certainty that the event that happened during surgery caused his myocardial infarction.* He was a person who was, by virtue of his coronary artery disease, was at risk of having a myocardial infarction. I think that the events that happened at the time of surgery simply made it more likely that he would die as a result of a myocardial infarction. But they also -- I think, you know, the issue of stress and atherosclerosis and myocardial infarction is not an issue where there's a clear consensus in the cardiology community. We were talking earlier about what causes a heart attack, and there's two things, and this is a simplification and there would be, in some rare syndromes, would be exceptions to these general rules, but there's two basic things. There's -- there's the development of plaque in the artery and then there's the inciting event, what happens that day that allows an artery that was, let's say, 70 percent narrowed to become a hundred percent narrowed. The classic atherosclerotic risk factors, hypertension, diabetes, smoking, family history, those are considered to be the main contributors to the development of plaque. On the topic of psychological stress, there's a general agreement and there's some data that being under psychological stress can play a role in accelerating atherosclerosis. I don't think that's the major role in terms of why he has atherosclerosis. There's also some evidence that people who are under psychological stress, it's a contributing factor. It can increase the risk of a cardiac event. So I think that what happened is -- played a role in his having a heart attack and made it less likely that he would survive the heart attack, *but I cannot say that it caused his heart attack.*[48]

This is not helpful. As Dr. Malosky admits, his testimony could just as easily be that Mr. Smith's heart attack was caused by his preexisting heart condition: Mr. Smith "was a person who was, by virtue of his coronary artery disease, . . . at risk of having a myocardial infarction."[49] Dr. Malosky's opinion would not help a jury decide whether Mr. Smith's death "would not have come but for" the surgery and the ten-minute lack of flow.[50] His opinion would not be helpful for

[48] Deposition of Steven Anthony Malosky at 51:9–53:9 (emphasis added).

[49] *Id.* at 51:25–52:2.

[50] *Raab*, 221 P.3d at 226 n.17.

deciding whether "there is a direct causal connection between the negligence and the injury."[51] Mrs. Smith seems to agree. Nowhere in the Opposition does she address this major shortcoming in Dr. Malosky's testimony.[52] This uncertainty is not something for the parties to work out in cross-examination. Evidence of this low quality and probative value should not be presented to a jury. Dr. Malosky, perhaps to his credit, has not and cannot state under oath that the September 2010 surgery and attendant complications caused Mr. Smith's death.

Given that Dr. Malosky's opinion is not helpful for establishing but-for cause, it is not helpful for establishing proximate cause. Dr. Malosky's opinion would not help the jury decide if Mr. Smith's injury "would have [occurred] even if [Defendants] had not been negligent."[53] As the Utah Court of Appeals stated, "no case has been found where the defendant's act could be called a proximate cause when the event would have occurred without it."[54] Dr. Malosky's opinion would not help the jury decide whether Mr. Smith's injuries would have occurred without the September 2010 surgery and its complications. Therefore, Dr. Malosky's opinion regarding causation is not helpful.

ii. Even if Dr. Malosky's testimony about Mr. Smith's death were helpful, it is not reliable.

To determine reliability, courts must make a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue."[55] Courts consider

[51] *Id.*

[52] Though she does respond that there can be "more than one cause of the same harm," Opposition at 15, but this relates to *proximate cause*. She does not address but-for cause.

[53] *Proctor*, 311 P.3d at 569 (alterations omitted).

[54] *Id.* (alterations omitted).

[55] *Daubert*, 509 U.S. 592–93.

various factors in making that assessment, including those listed in the Advisory Committee Notes to the 2000 Amendments to Federal Rule of Evidence 702. Those, in part, include:

> (1) Whether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying.
> (2) Whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion.
> (3) Whether the expert has adequately accounted for obvious alternative explanations.
> (4) Whether the expert is being as careful as he would be in his regular professional work outside his paid litigation consulting.[56]

First, the substance of Dr. Malosky's testimony regarding the cause of Mr. Smith's death aligns with his research and practice outside this litigation. His curriculum vitae confirms his extensive professional credentials as a cardiologist. Dr. Malosky has been a practicing cardiologist since July 1997.[57] Between July 1993 and June 1997, Dr. Malosky completed two fellowships, first a cardiovascular diseases fellowship and then an interventional cardiology fellowship, both at the Hospital of the University of Pennsylvania.[58] Although Dr. Malosky's list of research and presentations is a little thin, it does show that he has been involved in relevant research independent of this litigation.[59]

Second, Dr. Malosky's causal analysis has a significant analytical gap that leads him to form an unfounded conclusion. Dr. Malosky observes that Mr. Smith had certain problems with his heart and that he had surgery that was intended to fix those problems. But the problems were not resolved, and Mr. Smith continued to decline until he ultimately died. Therefore, according

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[56] Advisory Committee Notes to the 2000 Amendments to Fed. R. of Evid. 702 (internal citations and quotation marks omitted).

[57] Exhibit Steve Malosky, MD Curriculum Vitae at 2, docket no. 149, filed May 12, 2017.

[58] *Id.* at 1.

[59] *Id.* at 2–3.

to Dr. Malosky, the surgery *necessarily* contributed to Mr. Smith's decline and eventual death.[60] He does not provide a basis to conclude that the relationship is causal and not merely corollary. The gap between Dr. Malosky's premises and conclusion is too large.

Third, Dr. Malosky fails to fully account for obvious alternative explanations of the cause of Mr. Smith's death. The parties each provide scholarly support for the survival rate of individuals who suffer cardiac arrest outside of a hospital setting.[61] Defendants' article states that the survival rate for those who suffer cardiac arrest outside of a hospital ranges from 1% to 3.2%.[62] Mrs. Smith's article says 10.6% survive.[63] Both numbers suggest that there is a strong likelihood Mr. Smith would not have survived the cardiac arrest because he was not in a hospital when it happened. In other words, even if the September 2010 surgery went smoothly, but Mr. Smith still suffered cardiac arrest eleven months later, he would at best have a 10.6% chance of surviving. This seriously undermines Dr. Malosky's opinion for causation.

Mr. Smith's own medical history is full of other, potentially sufficient causes. Another expert gives a succinct summary of Mr. Smith's conditions that existed before the September 2010 surgery:

> Mr. Smith, a ranch hand and a former coal miner, had a medical history that included high cholesterol, asthma, pneumoconiosis (black lung disease), chronic bronchitis, laryngeal cancer with radiation (2004), rectal cancer with resection, radiation and chemotherapy (2003), and lung cancer with wedge resection and chemotherapy (2005). He was a 1.5 to 3 pack a day smoker and had severe chronic obstructive pulmonary disease (COPD) (including chronic bronchitis and

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[60] Opposition at 12–13 (citing and summarizing Dr. Malosky's report and deposition).

[61] Motion at 8; Opposition at 16.

[62] Motion at 8; *see* Marc Eckstein et al., Cardiac Arrest Resuscitation Evaluation in Los Angeles: CARE-LA, 45(5) Annals of Emergency Medicine 504 (May 2005), available online at https://www.researchgate.net/publication/7881986_Cardiac_arrest_resuscitation_evaluation_in_Los_Angeles_CARE-LA.

[63] Opposition at 16; *see* Dariush Mozaffarian, et al., HEART DISEASE AND STROKE STATISTICS—2016 UPDATE: A REPORT FROM THE AMERICAN HEART ASSOCIATION 5 (2016), available online at http://circ.ahajournals.org/content/circulationaha/early/2015/12/16/CIR.0000000000000350.full.pdf.

> emphysematous changes). His family history was significant in that his father died of heart disease.[64]

Despite this background, Dr. Malosky states that "it is more likely than not that proper and uninterrupted forward arterial flow during his heart valve replacement surgery would have *prevented*" a "deterioration of heart muscle strength," the "substantial worsening of Mr. Smith's congestive heart failure syndrome," "injury to the brain due to prolonged lack of oxygenated blood flow to the brain," and ultimately Mr. Smith's death.[65]

Dr. Malosky's report goes further than his deposition. As quoted at length above, Dr. Malosky "couldn't say with certainty that the event that happened during surgery caused his myocardial infarction."[66] But in his report, Dr. Malosky lists the various postoperative injuries, *including Mr. Smith's death*, and then states that a surgery without incident more likely than not would have prevented "the above-described injuries."[67] Dr. Malosky arrives at this conclusion without any reference to methodology. Mrs. Smith's arguments that Dr. Malosky took into account the preexisting health issues are not convincing. Her memorandum again refers to Mr. Smith's condition before and after the surgery.[68] But she does not show that Dr. Malosky took into account the many health issues Mr. Smith was facing and their possible role in Mr. Smith's ultimate decline and death.

Therefore, Dr. Malosky's testimony about the causal connection between the surgery, the ten or eleven minutes without forward flow, and Mr. Smith's death is excluded. It is not allowed at trial, and it will not be considered in the outstanding motions for summary judgment.

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[64] Report of C. Alan Brown, M.D. at 3, docket no. 149, filed May 12, 2017.

[65] Dr. Malosky Report at 1 (emphasis added).

[66] Deposition of Steven Anthony Malosky at 51:23–25.

[67] Dr. Malosky Report at 1.

[68] Opposition at 12–14.

2. Dr. Malosky's opinion that Mr. Smith suffered a perioperative myocardial infarction is not reliable.

The autopsy report states that Mr. Smith's heart had no "fibrotic areas consistent with an old infarct present."[69] In other words, there was no postmortem evidence that Mr. Smith had suffered a heart attack at an earlier date.[70] Dr. Malosky, however, determined that Mr. Smith had suffered a heart attack during the 2010 surgery (*i.e.*, perioperative myocardial infarction) based on Mr. Smith's post-surgery troponin levels and a post-surgery electrocardiogram.[71]

Defendants argue that Dr. Malosky's opinion that Mr. Smith's heart was damaged due to the lack of circulation during his surgery is not helpful or reliable because it "contradicts and ignores the results of an autopsy that revealed no significant scarring to Mr. Smith's heart muscle."[72]

There appears to be near consensus that an autopsy is the diagnostic gold standard,[73] especially for diagnosing myocardial infarctions.[74] Mrs. Smith apparently agrees. She does not contradict the Defendants' and the articles' characterizations of autopsy. Instead, she argues that Dr. Malsoky's contrary findings create a factual issue for the jury to decide.[75]

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[69] Surgical Pathology Report, docket no. 149, filed May 12, 2017.

[70] Plaintiff appears to be conflating the two alleged myocardial infarctions. There is the alleged myocardial infarction that is the immediate cause of his death. The parties do not seem to dispute that this happened. And there is the alleged perioperative myocardial infarction—the one that allegedly occurred during the September 2010 surgery. This second myocardial infarction is the one in dispute. The Autopsy Report distinguishes between these two alleged myocardial infarctions in a way that makes it unnecessary to address Plaintiff's argument.

[71] Deposition of Steven Anthony Malosky at 143:14–144:7.

[72] Motion at 10.

[73] RW Giard, et al., *[Truth after death]*, N. Tijdschr Geneeskd, English abstract available at https://www.ncbi.nlm.nih.gov/pubmed/10590770; I. Pakis, et al., Comparison of the clinical diagnosis and subsequent autopsy findings in medical malpractice, 31(3) Am. J. Forensic Med. Pathol., 218 (2010) available at https://www.ncbi.nlm.nih.gov/pubmed/20473143; M. Costache, Clinical or Postmortem? The Importance of the Autopsy; a Retrospective Study, 9(3) Maedica – a Journal of Clinical Medicine, 261 (2014).

[74] *See* I. Pakis, et al. *supra* note 70.

[75] Opposition at 7.

Trial courts are the gatekeepers of expert testimony.[76] They should exclude expert testimony that uses methods not generally accepted[77] or where an expert is not "being as careful as he would be in his regular professional work outside his paid litigation consulting."[78] Expert testimony cannot be used as a springboard for jury consideration of an unsubstantiated theory.

Dr. Malosky's methods are not generally accepted. There is no indication (*e.g.*, peer reviewed research) that clinical diagnostic indicators are in some instances more reliable than autopsy results. Indeed, it seems unlikely that in any setting other than this litigation Dr. Malosky would rely on the clinical diagnostic indicators over an autopsy. To allow the jury to hear Dr. Malosky's opinion on this point would be to allow the jury to hear conclusions based on inferior diagnostic metrics. This will not be permitted.

Therefore, Dr. Malosky's testimony about the alleged perioperative myocardial infarction is excluded. This does not mean, as Mrs. Smith properly points out,[79] that Dr. Malosky is generally precluded from testifying that Mr. Smith's heart was injured during the September 2010 surgery. A copy of Dr. Malosky's report is attached to this order. The excluded portions have red strikethrough and other indicators. Dr. Malosky may testify regarding the remaining portions of the report.

3. Dr. Malosky's opinion about Mr. Smith's alleged neurological injury is excluded because he is not qualified to offer it and because it is not reliable.

Dr. Malosky opines that "Mr. Smith suffered an injury to the brain due to prolonged lack of oxygenated blood flow to the brain."[80] Defendants argue that Dr. Malosky's opinion regarding

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[76] *Daubert*, 509 U.S. at 597.

[77] *Id.* at 594.

[78] Advisory Committee Notes 2000 Amendments.

[79] Opposition at 8.

[80] Dr. Malosky Report at 1.

any alleged neurological injury to Mr. Smith should be excluded because he is not qualified to opine on neurological injuries[81] and that even if he were, his opinion is not based on reliable methodology.[82]

To qualify as an expert, the expert must have "such skill, experience or knowledge in that particular field as to make it appear that his opinion would rest on substantial foundation and would tend to aid the trier of fact in his search for truth."[83] It is not enough for the expert to have some marginal familiarity with the subject area:[84] "merely possessing a medical degree is not sufficient to permit a physician to testify concerning any medical-related issue."[85]

Dr. Malosky is not qualified to opine on Mr. Smith's alleged neurological injuries. Dr. Malosky candidly admits that he is "not an expert on the neuropathology literature."[86] Even though Dr. Malosky bases his opinion on his "own experience with . . . patients who had cardiac arrest,"[87] he does not indicate any "knowledge, skill, experience, training, or education" that would qualify him to diagnose neurologic injuries.

But even if Dr. Malosky were qualified to opine on Mr. Smith's alleged neurological injuries, his methodology is flawed. Dr. Malosky reviews notes and comments of various individuals who met with Mr. Smith after the September 2010 surgery and formed his decision based on their descriptions and assessments. Specifically, Dr. Malosky opines that Mr. Smith

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[81] Motion at 13–15.

[82] *Id.* at 15–18.

[83] *LifeWise Master Funding v. Telebank*, 374 F.3d 917 (10th Cir. 2004) (internal quotation marks omitted).

[84] *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10th Cir. 2001).

[85] *Id.*

[86] Deposition of Steven Anthony Malosky at 40:22–23.

[87] *Id.* at 39:17–20.

suffered from hypoxic encephalopathy.[88] But in the autopsy of Mr. Smith's brain, there is no sign of any hypoxic encephalopathy.[89] Dr. Malosky's explanation for the disparity between his diagnosis and the autopsy does not bespeak any methodology:

> if a person has a typical event that would commonly cause hypoxic encephalopathy and he's seen multiple times by multiple different providers, all of whom feel, including a neurologist, that he has an encephalopathy, if the neuropathologist [i.e. the doctor performing the brain autopsy] says I don't see any sign here of injury, . . . I interpreted that to mean he had a mild encephalopathy."[90]

There is no basis for this opinion. It is not clear what led him to believe that when a neuropathologist sees no sign of injury in an autopsy but others—in a clinical setting—believe there may have been injury, that the injury necessarily must have been a mild version that would not show up in an autopsy. Dr. Malosky offers no methodological bridge, only speculation. He continues:

> I'm not an expert on the neuropathology literature. *I wondered -- or I should say I thought* that you could have a mild encephalopathy from a hypoxic injury and would not necessarily see scarring findings on pathology either because of sampling error or because a lot of the neuropathology findings that are described were described in cases where people had grievous injuries and died within a few days or a month or so of their injury from coma and vegetative state. His injury was not as severe as that. So I did see the neuropathologist's report, but I didn't think that that report in and of itself obviated what happened and then the clinical course over the ensuing 11 months.[91]

[88] *Id.* at 39:20.

[89] Exhibit 10 Dr. Heidingsfelder Autopsy Report at 1, docket no. 149, filed May 12, 2017 ("There is no evidence of ischemia, infection, or neoplacia.").

[90] Deposition of Steven Anthony Malosky at 40:14–40:21.

[91] *Id.* at 40:22–41:10 (emphasis added).

Dr. Malosky is not "being as careful as he would be in his regular professional work outside his paid litigation consulting."[92] A jury has no use for "I wondered – or I should say I thought,"[93] especially from someone whose expertise lies elsewhere.

Therefore, Dr. Malosky's testimony regarding the alleged neurological effect of the September 2010 surgery on Mr. Smith is excluded.

4. Dr. Malosky may state the factual bases for his opinions.

An expert may of course "base an opinion on facts or data in the case that the expert has been made aware of or personally observed."[94] And the expert can inform the jury of those bases. The expert, however, cannot take the place of a fact witness.

Therefore, Dr. Malosky may indicate what he relied on to form his opinions. He may not give a general narration of Mr. Smith's health before, during, and after the surgery.

ORDER

IT IS HEREBY ORDERED that Terumo Cardiovascular Systems Corporation's Motion to Exclude Steve Malosky[95] is GRANTED. A copy of Dr. Malosky's report is attached to this order. The portions now excluded have red strikethrough and other indicators. Dr. Malosky may testify regarding the remaining portions of the report.

Dated July 12, 2017.

BY THE COURT:

David Nuffer
United States District Judge

[92] Rule 702 Advisory Committee Notes 2000 Amendments.

[93] Deposition of Steven Anthony Malosky at 40:23.

[94] Fed. R. Evid. 703.

[95] Docket no. 149, filed May 12, 2017.